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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/565,438	01/20/2006	Bertrand Cosson	0510-1133	2184

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EXAMINER
AUDET, MAURY A

ART UNIT	PAPER NUMBER
1654	

MAIL DATE	DELIVERY MODE
04/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,438	COSSON ET AL.	
	Examiner	Art Unit	
	MAURY AUDET	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/20/06*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-40* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 January 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

I. Claims 1-6, drawn to a peptide inhibitor of the translation of proteins, characterised in that its length is up to 250 amino acids and in that it comprises an amino acid sequence possessing at least 85% identity with the amino acid sequence of SEQ ID NO: 1.

II. Claims 7-8 and 37, drawn to a fusion polypeptide specifically inhibiting the translation of a target polynucleotide of interest, characterised in that said polypeptide comprises a a peptide inhibitor of the translation of proteins, characterised in that its length is up to 250 amino acids and in that it comprises an amino acid sequence possessing at least 85% identity with the amino acid sequence of SEQ ID NO: 1 fused with an RNA binding protein.

III. Claims 9-17, and 29, drawn to a nucleic acid comprising a polynucleotide coding for a peptide inhibitor of the translation of proteins, characterised in that its length is up to 250 amino acids and in that it comprises an amino acid sequence possessing at least 85% identity with the amino acid sequence of SEQ ID NO: 1 or fusion polypeptide comprising the same OR a kit therefore OR a control system of the translation of a target polynucleotide of interest comprising a fusion polypeptide specifically inhibiting the translation of a target polynucleotide of interest, characterised in that said polypeptide comprises a peptide inhibitor of the translation of proteins, characterised in that its length is up to 250 amino acids and in that it comprises an amino acid

sequence possessing at least 85% identity with the amino acid sequence of SEQ ID NO: 1 fused with an RNA binding protein.

IV. Claims 18, 22-23, 31-33, and 38-40, drawn to a recombinant cloning or expression vector comprising a nucleic acid comprising a polynucleotide coding for a peptide inhibitor of the translation of proteins, characterised in that its length is up to 250 amino acids and in that it comprises an amino acid sequence possessing at least 85% identity with the amino acid sequence of SEQ ID NO: 1 or fusion polypeptide comprising the same OR a kit for the control thereof OR a control system comprising a recombinant expression vector comprising a nucleic acid of the translation of a target polynucleotide of interest comprising a fusion polypeptide specifically inhibiting the translation of a target polynucleotide of interest, characterised in that said polypeptide comprises a peptide inhibitor of the translation of proteins, characterised in that its length is up to 250 amino acids and in that it comprises an amino acid sequence possessing at least 85% identity with the amino acid sequence of SEQ ID NO: 1 fused with an RNA binding protein.

V. Claims 24-26, drawn to a prokaryotic or eukaryotic host cell comprising a nucleic acid of the translation of a target polynucleotide of interest comprising a fusion polypeptide specifically inhibiting the translation of a target polynucleotide of interest, characterised in that said polypeptide comprises a peptide inhibitor of the translation of proteins, characterised in that its length is up to 250 amino acids and in that it comprises an amino acid sequence possessing at least 85% identity with the amino acid sequence of SEQ ID NO: 1 fused with an RNA binding protein OR control system thereof.

VI. Claims 27-28, drawn to a method for the in vitro control of the translation of a target

polynucleotide of interest comprising a fusion polypeptide specifically inhibiting the translation of a target polynucleotide of interest, characterised in that said polypeptide comprises a peptide inhibitor of the translation of proteins, characterised in that its length is up to 250 amino acids and in that it comprises an amino acid sequence possessing at least 85% identity with the amino acid sequence of SEQ ID NO: 1 fused with an RNA binding protein.

VII. Claims 34-36, drawn to a method for the control of the translation of a target polynucleotide of interest comprising providing a control system comprising a first nucliec acid and a second nucleic acid comprising a fusion polypeptide specifically inhibiting the translation of a target polynucleotide of interest, characterised in that said polypeptide comprises a peptide inhibitor of the translation of proteins, characterised in that its length is up to 250 amino acids and in that it comprises an amino acid sequence possessing at least 85% identity with the amino acid sequence of SEQ ID NO: 1 fused with an RNA binding protein.

Lack of Unity

An international and a national stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept ("requirement of unity of invention"). Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. An international or a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) a product and a process specially adapted for the manufacture of said product; or (2) a product and a process of use of said product; or (3) a product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) a process and an apparatus or means specifically designed for carrying out the said process; or (5) a product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the

category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c).

Peptide Markush Group-Lack of Unity

The inventions contain the technical feature of a peptide inhibitor of the translation of proteins, characterised in that its length is up to 250 amino acids and in that it comprises an amino acid sequence possessing at least 85% identity with the amino acid sequence SEQ ID NO: 1 (from the south african aquatic frog, Xenopus laevis). However, the technical feature is not novel, and thus does not constitute the required "special" status as a technical feature, since a peptide bearing 250 amino acid having SEQ ID NO: 1 (e.g. at least 85% identity to) is known in the art. See, merely by example of such peptides falling within the genus peptide claimed:

1. A 90-mer peptide bearing 91.4% identity to present SEQ ID NO: 1 (Penn et al., US 2003/194704 A1 (priority date 3/3/02 versus Applicant's 7/21/03); claim 45, SEQ ID NO: 29440; see "Sequence Listing" @ http://seqdata.uspto.gov/sequence. html?DocID-200309194704); and

2. A 152-mer peptide also bearing 91.4% identity identity to present SEQ ID NO: 1 (Mintz et al., US 20070083334A1 (priority date 9/14/01 versus Applicant's 7/21/03); SEQ ID NO: 879360; see "Sequence Listing" @ http://seqdata.uspto.gov/?pageRequest=doc Detail&DocID=US20070083334A1).

Thus, the inventions lack unity.

Requirement for a Peptide Inhibitor or Fusion Polypeptide or Nucleic Acid Election as the Invention

Since SEQ ID NO: 1 is known, a search of any peptide thereto, bearing any modification within a 15% variance, within a peptide up to 250 amino acid residues, would constitute an individual and distinct search thereof; as no fixed, substantial core has been identified which could be coextensively searched, since a search of the known core will naturally bring up all the art on the known core. Equating to an undue search burden of any all such peptides (or fusion peptide or nucleic acid thereto). Since an individual sequence and/or structure search is required of each compound of the invention. Therefore, irrespective of which Group is elected as the invention, Applicant must elect a single peptide sequence or fusion peptide or nucleic acid, as the invention, to which the elected Invention group will be searched.

This requirement is not to be taken as an election of species, but rather as an election of a single invention, since each compound is assumed to be a patentably distinct invention, in the absence of evidence to the contrary.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CRF 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

In re Ochiai/Brouwer Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached on M-Th. 7AM-5:30PM (10 Hrs.).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MA, 3/19/2008

/Maury Audet/
Examiner, Art Unit 1654